

Guidelines for clinical trial protocols for interventions involving artificial intelligence: the SPIRIT-AI extension

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Abstract

The SPIRIT 2013 statement aims to improve the completeness of clinical trial protocol reporting by providing evidence-based recommendations for the minimum set of items to be addressed. This guidance has been instrumental in promoting transparent evaluation of new interventions. More recently, there has been a growing recognition that interventions involving artificial intelligence (AI) need to undergo rigorous, prospective evaluation to demonstrate their impact on health outcomes. The SPIRIT-AI (Standard Protocol Items: Recommendations for Interventional Trials–Artificial Intelligence) extension is a new reporting guideline for clinical trial protocols evaluating interventions with an AI component. It was developed in parallel with its companion statement for trial reports: CONSORT-AI (Consolidated Standards of Reporting Trials–Artificial Intelligence). Both guidelines were developed through a staged consensus process involving literature review and expert consultation to generate 26 candidate items, which were consulted upon by an international multi-stakeholder group in a two-stage Delphi survey (103 stakeholders), agreed upon in a consensus meeting (31 stakeholders) and refined through a checklist pilot (34 participants). The SPIRIT-AI extension includes 15 new items that were considered sufficiently important for clinical trial protocols of AI interventions. These new items should be routinely reported in addition to the core SPIRIT 2013 items. SPIRIT-AI recommends that investigators provide clear descriptions of the AI intervention, including instructions and skills required for use, the setting in which the AI intervention will be integrated, considerations for the handling of input and output data, the human–AI interaction and analysis of error cases. SPIRIT-AI will help promote transparency and completeness for clinical trial protocols for AI interventions. Its use will assist editors and peer reviewers, as well as the general readership, to understand, interpret and critically appraise the design and risk of bias for a planned clinical trial. The CONSORT-AI and SPIRIT-AI extensions improve the transparency of clinical trial design and trial protocol reporting for artificial intelligence interventions.